



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/763,876

01/23/2004

Abraham J. Domb

PG 102

6009

23579

7590

01/22/2010

Pabst Patent Group LLP

1545 PEACHTREE STREET NE

SUITE 320

ATLANTA, GA 30309

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

01/22/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/763,876	<b>Applicant(s)</b> DOMB, ABRAHAM J.	
	<b>Examiner</b> BLESSING M. FUBARA	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,6-10 and 15-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-10 and 15-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>10/15/09</u> .                           |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application  |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____.                          |

### **DETAILED ACTION**

The examiner acknowledges receipt of amendment and remarks filed 10/23/09. Claims 1 and 17 are amended. Claims 1-3, 6-10 and 15-27 are pending.

#### **Interview of 10/15/2009:**

Attorney Michael J. Terapane and the examiner held an interview on 15<sup>th</sup> Oct. 2009 to discuss the pending claims and the prior art of record. The suggestion was for the claims to be amended in such a way as to distinguish the claims over Storey. A copy of the interview summary is attached.

#### ***Response to Arguments***

1. Previous rejections that are not reiterated herein are withdrawn. For example, the rejection of the claims based on the original specification not envisioning the copolymer comprising anhydride monomers or oligomers or polymers or copolymers separated by random ester bonds is withdrawn in view of the amendment. Although, polyester anhydride should contain random or regularly spaced anhydride and ester bonds, the rejections of claims 1-3 over Peterson is withdrawn because of the disclosure of generic polyester anhydride. The rejection of claims 1-3, 6, 7, 15-19, 21, 22 and 25-27 under 35 U.S.C. 103(a) as being unpatentable over Storey et al. (US 5,756,652) in view of Franson et al. (US 5,859,271) or Negishi et al. (US 5,480,787) is also withdrawn in view of the requirement of amended claim 17 that the poly(ester-anhydride) comprises monomers derived from ricinoleic acid and sebacic acid.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1618

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-3, 6-10 and 15-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection.

5. The specification as filed does not envision random ester bonds along the polyanhydride backbone. Page 15, lines 8 and 12, the only paragraph of the original specification that talks about random bonds discloses “polymer based on random anhydride ester bonds” and “pure anhydride bonds or random mixed ester anhydride bonds.” The examiner cannot find in the original specification where it is said that the poly(ester-anhydride) co-polymer comprises ester bonds along the polyanhydride backbone according to what is now claimed in instant claims 1 and 17.

6. The rejection may be overcome by deleting limitations that are not envisioned by the as filed specification.

7. Claims 17-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1618

8. Amended claim 17 states that "monomers" are "derived from ricinoleic acid and sebacic acid." Ricinoleic acid and sebacic acids are monomers and it is unclear how monomers can be derived from monomers.

9. Applicant's specification suggests that the poly(ester anhydride) having random anhydride ester bonds or random mixed ester anhydride bonds are derived from reacting poly(sebacic acid) and ricinoleic acid in a one pot reaction (see page 15, lines 6-13 of the instant specification; instant claims 6,8 and 15).

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 3, 6, 7 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Storey et al. (US 5,756,652).

12. Storey discloses biodegradable poly(ester-anhydrides)(abstract) as implants for controlled release of bioactive substances (column 1, lines 6-11; column 5, lines 15-22). Storey discloses poly(ester-anhydride having a single anhydride function within the interior of the polyester backbone (column 6, line 32; column 7, lines 16-19) indicates that a poly(ester-anhydride) has both an anhydride and ester linkages in the backbone. Storey further discloses poly(ester-anhydride) that contains variable number of anhydride units along the polymer backbone (column 6, lines 47, 48; column 9, line 49 to at least line 54), which again depicts the presence of anhydride and ester functional units in the backbone of the polymer. When the

Art Unit: 1618

polymer contains the bioactive substance, claim 1 is met. The form suitable for injection is any form suitable and the Storey polymer is would be suitable for injection because it is for implantation so that claim 3 is met. The polyester anhydride compound according Storey comprises 2-20 polyester segments that are covalently bound through anhydride linkages and the polyester segment components comprise homopolymer or copolymer or terpolymer of biocompatible hydroxyl acids such as lactic acid, glycolic acid,  $\epsilon$ -hydroxycaproic acid (column 3, lines 22-44) with the hydroxyacid meeting the hydroxyl acids, such as glycolic acid,  $\epsilon$ -hydroxycaproic acid and  $\gamma$ -hydroxy valeric acid, of claims 6, 7 and 25. The teaching that the 2 to 20 polyester segments are bound through anhydride linkages suggests that the anhydride are separated by random polyester bonds so that the anhydride linkages being separated by random polyester linkages in claim 1 are met. Storey contemplates the presence of multiple anhydride linkages (column 3, lines 64, 65) and variable number of anhydride units along the polymer backbone (column 9, lines 49-53).

### ***Response to Arguments***

13. Applicant's arguments filed 10/23/09 have been fully considered but they are not persuasive.

14. Applicant has indicated that during the interview held on 15<sup>th</sup> October 2009, the examiner agreed that Storey's poly(ester-anhydride) has anhydride bond along the polyester backbone and that the examiner agreed that Storey does not explicitly or inherently disclose the polymers of the claimed composition.

15. Response: The examiner disagrees. The examiner suggested that the claims be amended in order to clearly distinguish the claims over the Storey art.

Art Unit: 1618

16. The present amendment does not distinguish the claim 1 from Storey because in Storey the ester and anhydride bonds are part of the backbone just as the claim. The anhydride units separates the ester units and put differently, the ester units separates the anhydride units and the units are not regularly spaced. Once one member **A** is randomly placed in relation to other members **B** in a row, other members **B** must necessarily also be placed randomly with respect to members **A**. Furthermore, linkages or bonds are either random or regular and when the art is silent as to what the other is, then random or regular is reasonably inherent.

17.

***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 1-3, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Storey et al. (US 5,756,652) in view Brem et al. (US 5,846,565).

20. Storey discloses poly(ester-anhydride having a single anhydride function within the interior of the polyester backbone (column 6, line 32; column 7, lines 16-19) indicates that a poly(ester-anhydride) has both an anhydride and ester linkages in the backbone. Storey further discloses poly(ester-anhydride) that contains variable number of anhydride units along the polymer backbone (column 6, lines 47, 48; column 9, line 49 to at least line 54), which again depicts the presence of anhydride and ester functional units in the backbone of the polymer.

Art Unit: 1618

Storey also discloses biodegradable poly(ester-anhydrides)(abstract) as implants for controlled release of bioactive substances (column 1, lines 6-11; column 5, lines 15-22) and claim 1 is met when the poly(ester-anhydride) contains a bioactive agent.

21. Storey teaches that the polyester-anhydride is used as bioresorbable implant, that the polyester-anhydride can be used alone or in combination with biologically active ingredient to effect prolonged release of the biologically active agent. Storey goes on to say that the use and construction of devices such as polymeric implant devices for sustained or prolonged delivery of biologically active agents are known in the art and that the polyester-anhydride can be substituted for prior art polymer in the preparation of “such devices” (see column 5, lines 15-22).

22. Storey does not disclose any specific biologically active agent as is recited in claims 2 and 10. However, polymeric implants such as polyanhydride and polyester polymer implants have been known to deliver active agents such as chemotherapeutic agents to the target areas (title; abstract; column 5, lines 23-27, 42-45; column 6, line 42 to column 9, line 56 of Brem); Brem contemplates encapsulating the drugs (column 5, lines 29-32). Brem also contemplates polymeric carrier as microparticles, microsphere and microcapsules for encapsulating the drug (column 11, lines 46-50) with the microcapsule, microparticles and microsphere meeting the requirements of claim 9.

23. Thus, taking the teachings of Storey where the polyester-anhydride is used in combination with biologically active agent to provide release of the active agent upon implantation, one having ordinary skill in the art at the time the invention was made would have reasonable expectation that the polyester-anhydride of Storey would release drugs upon



Art Unit: 1618

implantation; drugs such as chemotherapeutic agents meeting the limitation of small drugs in claims 2 and 10.

***Response to Arguments***

24. Applicant's arguments filed 10/23/09 have been fully considered but they are not persuasive.

25. Applicant states that the examiner agreed in the interview of 15<sup>th</sup> October 2009 that Brem does not cure the deficiencies of Storey and as such claims 1, 3, 9, 10, 17, 20, 23 and 24 are not obvious over Storey in view of Brem.

26. Response: The examiner disagrees. The examiner recollects what was stated in the interview summary that the claims would be amended in such a way to overcome the Storey reference (see attached interview summary from 15<sup>th</sup> of October 2009). However, the amendment does not overcome the Storey reference and claims 1-3, 9 and 10 are obvious over Storey in view of Brem.

27. Suggestion:

28. It is suggested that applicant look to page 15, lines 6-13 of the instant specification for the disclosure of random anhydride ester bonds or random mixed ester anhydride bonds for poly(ester-anhydride) copolymer of applicant's invention having random bonds. The generic claims 1 and 17 may be amended in the lines of what applicant has disclosed as it's invention on page 15, lines 6-13 to overcome the rejection under 35 USC 112, 1<sup>st</sup> and to also include the process of formation of the poly(ester-anhydride) copolymer from PSA and RA as described in

Art Unit: 1618

the specification and as attempted to be claimed in amended claim 17, which will move the claims closer to allowance.

29. No claim is allowed.

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

31.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m..

Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/  
Primary Examiner, Art Unit 1618